

Notice of Allowability

Application No.

10/776,521

Examiner

BENJAMIN P. BLUMEL

Applicant(s)

FLECHTNER ET AL.

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to applicant's response of January 18, 2008.
2. ☒ The allowed claim(s) is/are 1,2,4-11,13-19 and 21-48.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date ____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>1/18/08</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input checked="" type="checkbox"/> Other <u>correction of inventorship & updated bib data sheet</u> . |

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

Claims 1, 2, 4-11, 13-19 and 21-48 are examined on the merits.

Election/Restrictions

Claims 1, 2, 4, 11, 13, 27, 28, 31, 34, 35 and 38-44 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 5-10, 14-19, 21-26, 29, 30, 32, 33, 36, 37 and 45-48, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on May 16, 2006 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 18, 2008 was filed after the mailing date of the final Office action on April 18, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

The declarations by Paul Slusarewicz, Sunil Mehta, (co-inventors) and Michael A. Yamin (worked for assignee) filed on January 18, 2008 under 37 CFR 1.131 is sufficient to overcome the Wieland et al. (US PGPub 2004/0071656) reference thereby extending the prior art date to December 26, 2001. Even though applicants have identified this declaration as under 37 CFR 1.132 it is being treated as a declaration under 37 CFR 1.131 since its purpose is to antedate the prior art referenced in the previous Office action.

Inventorship

In view of the papers filed January 18, 2008, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by deleting the following inventors: Jessica B. Flechtner, Kenya Prince-Cohane, Sofija Andjelic and Brian H. Barber, while retaining Paul Slusarewicz and Sunil Mehta as co-inventors.

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The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Adriane M. Antler on April 8, 2008. The following amendments are made to clarify antecedent basis of the claimed invention.

The application has been amended as follows:

In claim 43, at line 1, "a plurality of the hybrid antigens" has been deleted and --more than one hybrid antigen-- inserted therefor.

In claim 44, at line 2, "hybrid antigens" has been deleted and --the more than one hybrid antigen-- inserted therefor.

Allowable Subject Matter

Claims 1, 2, 4-11, 13-19 and 21-48 are allowed.

The following is an examiner's statement of reasons for allowance: the claimed invention is free of the art. The closest teachings to that of the claimed inventions are that of McCarty et al. (Journal of Molecular Biology, 1996) which teach residues 1-8 of SEQ ID NO: 419 (RKLFFNLR), Gragerov et al. (Journal of Molecular Biology, 1994) which teach a similar sequence (NLLRLTG) to that of SEQ ID NO: 417 and Fourie et al.

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(Journal of Biological Chemistry, 1994) which teach a similar sequence (FYQLAKTCPV) to that of SEQ ID NO: 186. Furthermore, even though the peptide of McCarty et al. is one residue short of the claimed sequence of SEQ ID NO: 419, no motivation is found in the prior art (prior to December 26, 2001 (see response to amendment above)) to add a tryptophan to the carboxy end of RKLFFNLR, thus resulting in SEQ ID NO: 419. Furthermore, the claimed methods of making and using the claimed hybrid antigens are supported and enabled through the multiple examples of the specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648